



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,798	02/12/2002	Hisao Hiramatsu	10873.872USWO	6236
52835	7590	11/10/2005	EXAMINER	
HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902-0902 MINNEAPOLIS, MN 55402			HYUN, PAUL SANG HWA	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/049,798	HIRAMATSU ET AL.
	Examiner Paul S. Hyun	Art Unit 1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 September 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-13 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 02 September 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>May 10, 2002</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments filed on 9/2/05 have been acknowledged. However, the rejection of the claims based on prior art cited in the first Office Action is sustained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammer et al. (U.S. Patent Application US 2001/0051377 A1).

Hammer et al. disclose a cartridge-based analytical instrument that conducts measurements as well as a method for conducting measurements using the instrument. The cartridge containers used with the measuring instrument are pre-loaded with samples and reagents (see [0008] Summary of the Invention) wherein the sample and the reagent are held separately within a cartridge, the sample held in system 76 and the reagent held in reagent pouch 98.

It appears that the Applicants are using the terms "special-purpose cartridges" and "general-purpose cartridges" to define cartridges that are associated with specific, programmed measurement conditions and unique measurement conditions that must be manually programmed by a user, respectively.

Although the Hammer et al. reference does not explicitly disclose the terms "special-purpose cartridges" and "general-purpose cartridges", the reference discloses that the instrument is capable of conducting measurements requiring various conditions (see [0008] and [0076]), the measurement protocol determined by the measurement conditions encoded on information carriers in the form of bar codes 106 located on the cartridges.

Moreover, the reference discloses a user input interface that receives data from the operator of the instrument (see [0012]). The user input interface works in conjunction with a tracking and control system that coordinates a rotary drive mechanism to conduct measurements. The presence of the user input interface suggests that the instrument is capable of manual operation by a user of the instrument wherein the user inputs information regarding measurement conditions of a cartridge following instructions outputted by the user interface.

It appears that the instrument disclosed by Hammer et al. is capable of accommodating the two types of cartridge containers as defined by Applicants. It appears that the instrument can accommodate cartridges that are automatically measured by the instrument by following the instructions encoded on the bar code. It also appears that the instrument can accommodate cartridges wherein the instructions for measurement are manually input by a user of the instrument into the user interface. Because it is well known in the art of labeling or tagging to simplify identification as much as possible for ease of recognition, it would have been obvious to provide the

absence of a bar code on the cartridges that require manual operation of the instrument in order to provide a visual indicator of the cartridge distinction.

The reference further discloses that the bar code 106 is read by a carrier identification means in the form of a bar code reader 200 to provide input of data which is specific to the particular cartridge. The American Heritage Dictionary of the English Language, Fourth Edition defines bar codes as "a series of vertical bars of varying widths, in which each of the digits zero through nine are represented by a different pattern of bars that can be read by a laser scanner." It appears that by utilizing bar codes, a specific, non-overlapping identification number is given to each cartridge disclosed in the Hammer et al. reference. This information is used by the tracking and control system of the analytical instrument to coordinate the rotary drive mechanism for the cartridge rotor plate and the actuators which operate against the flexible septums and flexible reagent pouches (see [0061]).

The reference also discloses a disk inlet 22 that can accept a floppy disk that communicates with a central processing unit (CPU) (not pictured) located in the upper housing cover 14. According to The American Heritage Dictionary of the English Language, Fourth Edition, a floppy disk is "a flexible plastic disk coated with magnetic material and covered by a protective jacket, used primarily by computers to store data magnetically." Hammer et al. disclose that the floppy disk can be inserted into the instrument to provide software updates as well as transport other data and information into and out of the central processing unit (see [0050]). Based on the disclosure, it

appears that that the floppy disk can also be used to execute the control program run by the instrument as well as store the measurement conditions for cartridges.

In regards to a measurement condition storage means, The Free On-Line Dictionary of Computing defines a CPU as "part of a computer that controls all other parts. The CPU also comprises memory, including RAM, cache, registers and ROM." Based on this definition, it appears that the CPU disclosed by Hammer et al. is capable of storing the measurement conditions in an organized manner, since it is well known that computers are capable of storing information in separate and easily identifiable folders. It would have been obvious to one of ordinary skill in the art to store the measurement conditions for each cartridge in separate folders for organizational purposes. For cartridges that lack a bar code, it appears that the information regarding their measurement conditions can be manually input into the input interface of the measuring equipment to be stored in a separate folder.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammer et al. in view of Petersen et al. (U.S. Patent Application US 2001/0012612 A1). Hammer et al. discloses the invention as mentioned, but it is silent towards a waste vessel disposed in the cartridge container to store waste liquid.

Petersen et al. discloses a method for analyzing fluid samples that utilizes a multi-vessel cartridge wherein chamber 68 is used to store waste. It would have been obvious to one of ordinary skill in the art to incorporate a waste vessel as taught by

Petersen et al. in the cartridge disclosed by Hammer et al. so that waste material from the analysis can be separated for easy disposal.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Devlin et al. (U.S. Patent Application US 2002/0064884 A1).

Response to Arguments

In light of the correction, the objection to the Drawings has been withdrawn.

In light of the amendment, the objection to claim 9 for reciting the claim in an improper multiple dependent form has been withdrawn.

Applicants' arguments with respect to the rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, as being indefinite, have been fully considered and are persuasive. The rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, has been withdrawn.

In regards to the rejection of claims 1-13 under 35 U.S.C. 103(a), Applicants' arguments filed on 09/09/2005 have been fully considered but they are not persuasive.

In regards to the amendments made to claim 4, the previously presented claim did not include what appears to be a typographical error corrected by the amendments. Since the amendments only corrected what appears to be a typographical error, the amendments did not affect the scope of the claim, and the rejection based on the

Hammer et al. reference cited in the first Office Action is still applicable to the amended claim.

In regards to the amendments made to claim 11, the amendments do not appear to affect the scope of the claim and therefore, the rejection based on the first Office Action is still applicable to the amended claim.

It appears that the Applicants are using the terms "special-purpose cartridges" and "general-purpose cartridges" to define cartridges that are associated with specific, programmed measurement conditions that are measured automatically and unique measurement conditions that must be manually programmed by a user, respectively.

Although the Hammer et al. reference does not explicitly disclose the terms "special-purpose cartridges" and "general-purpose cartridges", the reference discloses that the tracking and control unit that automates the measuring process includes a user input interface for receiving data input from the operator of the instrument (see [0012]). It appears that an operator of the instrument can manually input the information carried on the bar code of a cartridge and manually operate the instrument. Therefore, it appears that the instrument disclosed by Hammer et al. is capable of accommodating the two types of cartridge containers as defined by Applicants.

In response to Applicants' argument that all the cartridges disclosed by Hammer et al. are preloaded with samples and reagents, while some of the cartridges disclosed by Applicants are loaded manually by a measurer, it appears that the two methods of loading a cartridge are obvious variations of one another. See *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958), a case in which the court held that broadly

providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.

In response to Applicants' argument that the instrument disclosed by Hammer et al. requires the utilization of bar codes in order to function, it appears that the instrument can also be manually operated and thus does not require bar codes. The reference discloses that the tracking and control unit that automates the measuring process includes a user input interface for receiving data input from the operator of the instrument (see [0012]). It appears that an operator of the instrument can manually input the measurement condition for a specific cartridge and manually operate the instrument. Although the bar codes are an important feature of the invention disclosed by Hammer et al., they do not appear to be a necessity. Therefore, the modification suggested in the prior Office Action appears to be feasible with reasonable expectation of success.

In response to Applicants' argument that the Hammer et al. reference does not teach/suggest a method, operational means, or a control program that decides whether a cartridge container is a special-purpose cartridge container or a general-purpose cartridge container, it is well known in the art of bar coding to alert the operator of the bar code reader, either in the form of a noise or a visual indicator, if a bar code cannot be read. It would have been obvious to one of ordinary skill in the art to configure the bar code reader to classify all cartridge containers lacking a bar code as "general-purpose cartridge containers" and classify all cartridge container that have a bar code as "special-purpose cartridge containers" so that the operator of the instrument can manually input the measurement conditions of cartridges that lack a bar code.

In response to Applicants' argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PSH 10/05/05


Jill Warden
Supervisory Patent Examiner
Technology Center 1700